Notice of Allowability	Application No.	Applicant(s)	
	10/810,352	METZ ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the communication filed 11/2/06*.

2. ☒ The allowed claim(s) is/are *115-160*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 2/7/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Applicant's election without traverse of the invention of Group I, claims 1-8, directed to the nucleic acid sequence encoding SEQ ID NO: 66 in the reply filed on November 2, 2006 is acknowledged.

The application has been amended as requested in the communication filed November 2, 2006. Accordingly, claims 1-114 have been deleted, and new claims 115-157 have been entered.

Claims 115-157 are pending.

Claims 115-140 read on the elected subject matter of now canceled claims 1-8. Claims 141-157 are limited and directed to the method of use of the nucleic acid of the elected subject matter of claims 115-140. Since the claimed nucleic acid is novel (see below), the restriction between the nucleic acid and its methods of use has been vacated.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Angela Dallas Sebor on November 20, 2006 and November 21, 2006.

The application has been amended as follows:

(I) Rewrite the following claims as shown below:

Claim 115 An isolated nucleic acid molecule comprising a nucleic acid sequence encoding an amino acid sequence that is at least 95% identical to SEQ ID NO:66, wherein the amino acid sequence has β-hydroxyacyl-ACP dehydrase (DH) activity.

Claim 119 The isolated nucleic acid molecule of Claim 115, wherein the nucleic acid molecule consists ~~essentially~~ of a nucleic acid sequence encoding SEQ ID NO:66.

Claim 123 A recombinant nucleic acid molecule comprising the nucleic acid molecule of Claim 115~~, operatively linked to at least one~~ and an expression control sequence.

Claim 124 A recombinant nucleic acid molecule comprising the nucleic acid molecule of Claim 118~~, operatively linked to at least one~~ and an expression control sequence.

Claim 125 A recombinant nucleic acid molecule comprising the nucleic acid molecule of Claim 120~~, operatively linked to at least one~~ and an expression control sequence.

Claim 126 A recombinant microbial or plant cell that expresses the recombinant nucleic acid molecule of Claim 123.

Claim 131 A recombinant microbial or plant cell that expresses the recombinant nucleic acid molecule of Claim 124.

Claim 136 A recombinant microbial or plant cell that expresses the recombinant nucleic acid molecule of Claim 125.

Claim 141 A method to produce at least one polyunsaturated fatty acid (PUFA), comprising culturing under conditions effective to produce the PUFA, a microorganism or a plant ~~an organism~~ that expresses a PKS system for production of PUFAs, wherein the microorganism or plant ~~an organism~~ expresses the recombinant nucleic acid molecule of Claim 123.

Claim 142 The method of Claim 141, wherein the microorganism or a plant ~~organism~~ produces a polyunsaturated fatty acid (PUFA) profile that differs from an organism that does not express the recombinant nucleic acid molecule ~~of Claim 123~~.

Claim 143 The method of Claim 142, wherein the organism produces docosahexaenoic acid (DHA), and wherein the production of DHA is increased in the microorganism or a plant ~~organism~~ as compared to an organism that does not express the recombinant nucleic acid molecule ~~of Claim 123~~.

Claim 144 The method of Claim 141, wherein the microorganism or a plant ~~organism~~ is a microorganism.

Claim 145 The method of Claim 141, wherein the microorganism or a plant ~~organism~~ is a plant.

Claim 146 A method to produce at least one polyunsaturated fatty acid (PUFA), comprising culturing under conditions effective to produce the PUFA, a microorganism or a plant ~~an organism~~ that expresses a PKS system for production of PUFAs, wherein the microorganism or plant ~~an organism~~ expresses the recombinant nucleic acid molecule of Claim 124.

Claim 147 The method of Claim 146, wherein the microorganism or a plant ~~organism~~ is a microorganism.

Claim 148 The method of Claim 146, wherein the microorganism or a plant ~~organism~~ is a plant.

Claim 149 A method to produce at least one polyunsaturated fatty acid (PUFA), comprising culturing under conditions effective to produce the PUFA, a microorganism or a plant ~~an organism~~ that expresses a PKS system for production of PUFAs, wherein the microorganism or plant ~~an organism~~ expresses the recombinant nucleic acid molecule of Claim 125.

Claim 150 The method of Claim 149, wherein the microorganism or a plant ~~organism~~ is a microorganism.

Claim 151 The method of Claim 149, wherein the microorganism or a plant ~~organism~~ is a plant.

Claim 155 A method to produce lipids enriched for docosahexaenoic acid (DHA), comprising culturing under conditions effective to produce the lipids, a Thraustochytrid microorganism that expresses the recombinant nucleic acid molecule of Claim 123 and that produces DHA, wherein the production of DHA is enriched in the ~~organism~~ Thraustochytrid microorganism as compared to in the absence of the expression of the recombinant nucleic acid molecule ~~of Claim 123~~.

Claim 156 A method to produce lipids enriched for docosahexaenoic acid (DHA), comprising culturing under conditions effective to produce the lipids, a Thraustochytrid microorganism that expresses the recombinant nucleic acid molecule of Claim 124 and that produces DHA, wherein the production of DHA is enriched in the ~~organism~~ Thraustochytrid microorganism as compared to in the absence of the expression of the recombinant nucleic acid molecule ~~of Claim 124~~.

Claim 157 A method to produce lipids enriched for docosahexaenoic acid (DHA), comprising culturing under conditions effective to produce the lipids, a Thraustochytrid microorganism that expresses the recombinant nucleic acid molecule of Claim 125 and that produces DHA, wherein the production of DHA is enriched in the ~~organism~~ Thraustochytrid microorganism as compared to in the absence of

the expression of the recombinant nucleic acid molecule ~~of Claim 125~~.

(II) Enter the new claims below:

Claim 158 An isolated recombinant cell that expresses the recombinant nucleic acid molecule of Claim 123.

Claim 159 An isolated recombinant cell that expresses the recombinant nucleic acid molecule of Claim 124.

Claim 160 An isolated recombinant cell that expresses the recombinant nucleic acid molecule of Claim 125.

Claims 115-160 are allowed.

The following is an examiner's statement of reasons for allowance: The specification teaches a gene cluster for the biosynthesis of polyunsaturated fatty acids (PUFA) from *Schizochytrium* sp. The genetic organization of said gene cluster are very similar to the organization of polyketide synthases such as those required for the biosynthesis of macrolactones in *Sterptomyces*. The specification enables the use of the gene cluster in producing fatty acids in microorganisms and plants. The claims are directed to the nucleic acid sequence encoding the amino acid sequence of SEQ ID NO: 66, which is a dehydrase domain, named DH2 in the specification. Since both the nucleic and amino acid sequences are free of prior art, the claims are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1656

***